IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

SISSY SIMMONS,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**CASE NO.: 3:04-1080**
	)	**JUDGE KNOWLES**
	)	
	)	
BLUECROSS BLUESHIELD OF TENNESSEE,	)	
	)	
	)	
Defendant.	)	

MEMORANDUM OPINION

I. Introduction and Background

Plaintiff Sissy Simmons filed this action in part for relief under the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1132(a)(1)(B).[1] Plaintiff alleges that she is insured under a medical policy issued by Defendant BlueCross BlueShield of Tennessee, Inc. ("BCBST"), and that BCBST erroneously denied her request for coverage for a medical procedure known as Autologous Chondrocyte Implantation ("ACI") surgery. ACI is also referred to as Autologuous Chondrocyte Transplant or ACT.[2]

This matter is before the Court upon Defendant's Motion for Judgment on the

[1] Plaintiff also claims that Defendant breached fiduciary duties to Plaintiff in violation of 29 U.S.C. § 1132(a)(2). Plaintiff has requested that the Court initially consider and rule upon her claims under § 1132(a)(1)(B). Thus, Plaintiff's claims under § 1132(a)(2) will not be discussed herein.

[2] In order to be consistent with the Administrative Record in this case, the Court will use both abbreviations in this Opinion to refer to the procedure.

Administrative Record and Supporting Memorandum (Docket Nos. 19, 20), and Plaintiff's Amended Motion for Judgment on the Administrative Record and Supporting Memorandum (Docket Nos. 36, 37). Additionally, Defendant has filed a Response to Plaintiff's Amended Motion for Judgment on the Administrative Record.[3] Docket No. 39.

The parties filed a Consent to allow a United States Magistrate to conduct any and all proceedings in this matter and order the entry of judgment in the case, and Judge Haynes subsequently referred this action to the undersigned pursuant to 28 U.S.C. § 636(c) and Fed. R. Civ. P. 73(b). Pursuant to the procedure set forth in *Wilkins v. Baptist Healthcare Sys., Inc.*, 150 F.3d 609, 619 (6th Cir. 1998), the following constitutes the Court's findings of fact and conclusions of law.

II. Findings of Fact

Plaintiff Sissy Simmons is a participant under a medical policy (the"Policy") administered by BCBST. The policy is an "employee welfare benefits plan" within the meaning of ERISA, 29 U.S.C. § 1002(1). BCBST has denied Mrs. Simmons coverage for a surgical procedure on her knee on the grounds that the procedure is "investigational." The plan is fully funded, and Defendant bears the financial burden of paying claims.

The Plan excludes from coverage, "[s]ervices or supplies that are . . . Investigational in nature." "Investigational Services" is defined as follows:

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[3] Plaintiff filed her original Motion for Judgment on the Administrative Record and Supporting Memorandum on March 25, 2005 (Docket Nos. 23, 24), the same day Defendant filed its Motion for Judgment on the Administrative Record and its Supporting Memorandum. That same day, Plaintiff also filed a Motion to Strike certain documents filed by Defendant as part of the Administrative Record. During a telephone conference call, Plaintiff's counsel had requested that, if the Court denied the Motion to Strike, they be allowed to file an Amended Motion for Judgment on the Administrative Record, and Plaintiff subsequently did so.

A drug, device, treatment, therapy, procedure . . . that does not meet the definition of Medical Necessity or;

a. cannot be lawfully marketed without the approval of the Food and Drug Administration ("FDA") when such approval has not been granted at that (sic) time of its use or proposed use, or

b. is the subject of a current Investigational new drug or new device application on file with the FDA, or

c. is being provided according to Phase I or Phase II clinical trial or the experimental or research portion of a Phase III clinical trial (provided, however, that participation in a clinical trial shall not be the sole basis for denial), or

d. is being provided according to a written protocol which describes among its objectives, determining the safety, toxicity, efficacy or effectiveness of that service or supply in comparison with conventional alternatives, or

e. is being delivered or should be delivered subject to the approval and supervision of an Institutional Review Board . . . as required and defined by Federal Regulations, or

f. The Office of Health Care Technology Assessment within the Agency for Health Care Policy and Research . . . has determined that the service or supply is either experimental or Investigational or that there is insufficient data to determine if it is clinically acceptable, or

g. in the predominant opinion of experts, as expressed in the published authoritative literature, that usage should be substantially confined to research settings, or

h. in the predominant opinion of experts, as expressed in the published authoritative literature, further research is necessary in order to define safety, toxicity, efficacy, or effectiveness of that Service

compared with conventional alternatives, or

i. the service or supply is required to treat a complication of an experimental or Investigational Service.

As quoted above, the term "Investigational Services" is defined in part as "[a] drug, device, treatment, therapy, procedure . . . that does not meet the definition of Medical Necessity . . ." The term "Medical Necessity" is defined in the plan as follows:

> **Medically Necessary or Medical Necessity** – Services which have been determined by the Plan to be of proven value for use in the general population. To be Medically Necessary a service must:
>
> a. have final approval from the appropriate government regulatory body;
>
> b. have scientific evidence permitting conclusions concerning the beneficial effect of the service on health outcomes;
>
> c. improve the net health outcome;
>
> d. be as beneficial as any established alternative;
>
> e. demonstrate the improvement outside the investigational setting; and not be an experimental or investigational service.

It is undisputed that the policy gives BCBST discretion in making benefit determinations. In fact, the Policy states in pertinent part as follows:

> **Our Medical Director has discretionary authority, in accordance with applicable ERISA standards, to make a determination concerning whether a service or supply is an experimental or Investigational Service.** If Our Medical Director does not Authorize the provision of a service or supply, it will not be a Covered Service. In making such determinations, Our Medical Director shall rely upon any or all of the following, at his or her discretion:
>
> (1) your medical records, or

(2) the protocol(s) under which proposed service or supply is to be delivered, or

(3) any consent document that You have executed or will be asked to execute, in order to receive the proposed service or supply, or

(4) the published authoritative medical or scientific literature regarding the proposed service or supply in connection with the treatment of injuries or illnesses such as those experienced by You, or

(5) regulation and other official publications issued by the FDA and HHS, or

(6) the opinion of any entities that contract with the Plan to assess and coordinate the treatment of Members requiring non-experimental or Investigational Services, or

(7) the findings of the BlueCross and BlueShield Association Technology Evaluation Center or other similar qualified evaluation entities.

(Emphasis added.)

Mrs. Simmons, a 41-year old mother of three, dislocated her kneecap during her teenage years. At that time, Mrs. Simmons underwent several surgeries to repair her knee. Unfortunately, over time, exertion on her knee has worn away the articular cartilage and Mrs. Simmons suffers pain and discomfort during everyday activities. Mrs. Simmons' knee condition affects "everyday activities from – housework, to activities with children, to not being able to stay in shape," and even simple tasks such as climbing stairs. Because of her relatively young age, Mrs. Simmons is not eligible for a total knee replacement.

In late Summer 2003, Mrs. Simmons was referred to Scott Gillogly, M.D. ("Dr. Gillogly"), a leading physician in the area of cartilage repair, who has preformed the ACI procedure over 230 times. Dr. Gillogly performed a knee arthroscopy and took a chondral

biopsy and concluded that Mrs. Simmons needed the ACI procedure.

ACI is a two-part procedure that regenerates hyaline-like cartilage and restores function to the joint. In the initial procedure, through arthroscopy, healthy cartilage is biopsied. Then, the biopsy of the healthy cartilage is sent to Genzyme, the sole FDA licensed cell-processing facility. From the biopsied cartilage, Genzyme grows millions of new cartilage cells and those cells are sent to the physician, who implants them into the defective area.

A. The Initial Denial of Benefits

In early September 2003, Dr. Gillogly contacted BCBST to obtain prior authorization for the ACI procedure for Mrs. Simmons. On October 8, 2003, BCBST responded to Dr. Gillogly's preauthorization request, indicating that ACI is "investigational" and, therefore, not covered under the Policy. Dr. Gillogly attempted to bring to BCBST's attention his opinion that ACI is not investigational.

Meanwhile, in early December 2003, Plaintiff filed a grievance with the Level I Grievance Committee of BCBST, seeking to have the ACI procedure covered by the Policy and paid for by BCBST. On January 7, 2004, the Level I Grievance Committee denied Plaintiff's request, referring Plaintiff to the definition of "investigational" contained in the Policy.

In the January 7, 2004 denial letter, BCBST advised Plaintiff of her right to seek review of the Level I Grievance Committee decision. On January 26, 2004, Plaintiff wrote the Level II Grievance Committee requesting reconsideration of the Level I denial. Thereafter, Plaintiff received notice that the Level II Grievance Committee of BlueCross BlueShield of Tennessee (the "Committee") would meet to hear her grievance and that she was entitled to participate in the hearing (the "Hearing"). She was advised that she would be able to: 1) describe her

complaint; 2) explain what she believed BCBST should do to address the complaint; 3) present witnesses or evidence; and 4) question any BCBST witnesses.

B. The Level II Grievance Hearing

The Hearing was held on March 9, 2004, and Plaintiff was represented by counsel at the Hearing. Because the Level I denial letter did not indicate on what grounds BCBST was relying in concluding that ACI is investigational, Plaintiff's counsel began the Hearing by requesting this information from the Committee. Specifically, Plaintiff was interested in knowing whether BCBST was relying on the definition of "investigational" in the Policy or whether BCBST was relying on the 2003 version of the Medical Policy Manual, in which Plaintiff's physician, Dr. Gillogly, was cited as a medical authority.

Jim Touse, Chair of the Committee, stated that the Policy definition was a factor, but the crux of the issue was the facts set forth in the Medical Policy Manual. The Medical Policy Manual concludes that ACI is "investigational" because it does not meet the following criteria: 1) scientific evidence must permit conclusions concerning the effect of the technology on health outcomes; 2) technology must improve the net health outcome; 3) technology must be as beneficial as any established alternatives; and 4) improvement must be attainable outside the investigational settings.

Mrs. Simmons' counsel called two medical experts to explain to the Committee why ACI is not "investigational" based on any valid criteria, but specifically not based on the express criteria delineated in the Medical Policy Manual. Dr. Gillogly, Mrs. Simmons' physician, testified first.[4] Dr. Gillogly explained the nature of Mrs. Simmons' condition and the negative

[4] The rules of administrative procedure did not require testimony to be under oath.

effect the condition is having on her day-to-day activities. Next, Dr. Gillogly explained that ACI is not investigational because it has been performed successfully over 8,000 times in the United States alone, it is approved by the FDA, and its safety and efficacy are well-established in the orthopaedic community. Then, Dr. Gillogly addressed each of the criteria listed above and delineated why each criteria is undoubtedly met by ACI.

Specifically, Dr. Gillogly stated: 1) that there are hundreds of published articles, including studies of patients 14-15 years after the procedure that establish the durability and efficacy of ACI, particularly in comparison to other procedures; 2) that ACI is cost effective because of the reduced potential for multiple treatments; 3) that it is a "no-brainer" that ACI is not only as beneficial as other alternatives, but more beneficial; and 4) that although there are investigations being done regarding chondral tissue repair for future therapy, ACI is not being conducted in an "investigational" setting. In conclusion, Dr. Gillogly indicated that the designation of ACI as "investigational" in the BCBST Medical Policy Manual may have been correct in 1996 or 1997, but that designation is no longer correct. In recent years, with all the newly available data on the procedure and its extensive use among orthopaedic surgeons, there is no meritorious basis for concluding that the ACI procedure is "investigational."

Mrs. Simmons' second witness, Allen Anderson, M.D. ("Dr. Anderson"), is a member of the Cartilage Registry Advisory Board, which is a group of eight physicians around the country who evaluate manuscripts from ACI procedures and track the results of people who have been treated using ACI. Dr. Anderson had not seen Mrs. Simmons and was not aware of her particular case, but testified, based on his extensive experience, about the non-investigational nature of the procedure.

Dr. Anderson explained the following facts: 1) there is a large body of scientific evidence on the efficacy of ACI, including information regarding some 2,000 patients in the Cartilage Repair Registry and a multitude of articles on ACI; 2) 70-90 percent of the patients that have the ACI procedure show improvement; 3) for larger lesions, such as the one Mrs. Simmons has, studies have shown that a minimum ACI is as beneficial as other alternatives and in many cases is more beneficial; and 4) based the over 8,000 ACI procedures that have been performed in the United States, it is clear that practicing orthopaedic surgeons provide patients with substantial improvement using this procedure. Dr. Anderson also echoed Dr. Gillogly's opinion that ACI was investigational 4 or 5 years ago, but now, ACI is a proven effective and non-investigational procedure. Dr. Anderson also discussed certain additional medical materials that were not before the Committee but that would provide the Committee with further evidence of the non-investigational nature of ACI.

As discussed above, during the Level II Grievance Committee Hearing, and apparently prior thereto, Defendant had advised Plaintiff that the BlueCross BlueShield Medical Policy Manual concluded that the ACI procedure was investigational. Presumably because that decision might have been binding upon the Level II Grievance Committee, the parties discussed the possibility of allowing the Medical Policy Committee to review its determination and to decide whether the Policy should be revised. In this regard, the Hearing Transcript reveals the following discussion:

> [By Mr. Barfield] I wondered if you could identify for us exactly what the investigational grounds that Blue Cross is relying upon in turning down Ms. Simmons' surgery.
>
> Mr. Touse: It's based on our medical policy, and the medical policy is developed through a committee structured through

research, etc. and obviously looks at the issues which are contained in the EOC but I – I don't – I can't talk to specifically which issues are involved.

Mr. Barfield: Well, is the medical policy – by that, are you talking about the Blue Cross-Blue Shield Medical Policy Manual which contains the – the discussion about ACI and concludes that it's investigational?

Mr. Touse: Yes.

Id. at 8.

. . .

Mr. Touse: I guess the question is we – and, you know, it has actually been discussed prior to this meeting, do you object to having this presented to the Committee to determine if the policy should be revised?

Mr. Barfield: Oh, of course, not.

Mr. Touse: Okay.

Mr. Barfield: We – we would be delighted. And by the Committee, you mean the – the Medical Policy Committee, right?

Mr. Touse: Yes.

Mr. Barfield: Yes. No, no, we do not object. We would be delighted for it to be presented to the Medical Policy Committee for – for review.

Id. at 26-27.

. . .

Mr. Barfield: Okay. And if I understood correctly Dr. Anderson's comment a moment ago that he is getting together some articles to send to Dr. Patric, those articles could be used in connection with the proceedings before the Medical Policy Committee; is that right?

Mr. Touse: Absolutely. That's the normal course. We – we do encourage providers to submit whatever information they think is relevant.

> Mr. Barfield: Okay. I might mention that we have included in the materials submitted for this hearing under Tabs 4-10 a number – no, seven articles – at least seven of the articles that we think are relevant to the issue, so I would ask that that be referred also to medical policy.
>
> Mr. Touse: We would do that, and, obviously, any additional information that Dr. Anderson and others would like to submit. I mean, you know, the bottom line, as I said at the beginning of this discussion, is we want to make sure we have all the facts and that we're making the appropriate decision. So any information that you could provide to us to be considered would be very helpful to our policy committee.
>
> Mr. Barfield: Okay.

Id. at 27-28.

. . .

> Mr. Barfield: Predetermination. Okay. Are there any other questions, Jim, for Ms. Simmons.
>
> Mr. Touse: No, I don't believe so, and I think in the interest of time we do appreciate your – as we said, I think does go to the medical policy, and if you don't object, what I would propose is we do send it to the Medical Policy Review Committee along with any additional information you'd like to submit.
>
> Mr. Barfield: Okay. I'd like to ask – and I'll follow up with Dr. Anderson to be sure he sends those materials to Dr. Patric, and I think that would complete the supplementation of the record. I am also happy to type up this transcript and submit it to you, Jim, for inclusion in the record and they can – so that the Medical Policy Committee could have the benefit of Dr. Gillogly's and Dr. Anderson's opinions here in the – in the hearing today. So if that's permitted, I'll be glad to do that.
>
> Mr. Touse: Okay. That would be very useful, in fact.

Id. at 30-31.

Thus, within 24 hours of the Hearing, the Level II Grievance Committee wrote Mrs. Simmons a letter stating that it concluded ACI was investigational "*pending review of the*

medical information submitted as well as additional medical information Dr. Anderson will be submitting to the Medical Policy Review Committee." (Emphasis added).

C. The Final Denial

On June 23, 2004, Plaintiff received a letter from Shelley Sullivan, a member of the Level II Grievance Committee, indicating that the Medical Policy Committee had determined that the procedure was "investigational" and, therefore, that Plaintiff's predetermination request was denied. The denial states that ACI is investigational and attaches the "updated" Medical Policy Manual. Thereafter, Plaintiff filed the instant lawsuit.

III. Conclusions of Law

When an ERISA Plan expressly provides discretion to the administrator in making eligibility decisions, the reviewing Court employs the arbitrary and capricious standard of review. *See Williams v. Int'l Paper Co.,* 227 F.3d 706, 711 (6th Cir. 2000) *citing Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 110-12 (1989).

The arbitrary and capricious standard is the "least demanding form of judicial review of administrative action." *McDonald v. Western-Southern Life Ins. Co.*, 347 F.3d 161, 169 (6th Cir. 2003) (internal citations and quotations omitted).

A decision is not arbitrary and capricious "when it is possible to offer a reasoned explanation, based on the evidence, for a particular outcome." *Williams,* 227 F.3d at 712 (internal quotation omitted).

An administrator's decision on eligibility for benefits is not arbitrary and capricious if it is "rational in light of the plan's provisions." *Miller v. Metropolitan Life Ins. Co.,* 925 F.2d 979, 984 (6th Cir. 1991).

In reviewing an administrator's decision under the arbitrary and capricious standard, the district court is strictly limited to the record before the administrator at the time the administrator made his decision. *Killian v. Health Source Provident Adm'r, Inc.*, 152 F.3d 514, 522 (6th Cir. 1998).

The Sixth Circuit has previously explained that the proper role of courts in ERISA cases is not "to hear and consider evidence not presented to the plan administrator in connection with a claim." *Perry v. Simplicity Engineering*, 900 F.2d 963(6th Cir. 1990). The *Perry* Court emphasized:

> In the ERISA context, the role of the reviewing federal court is to determine whether the administrator or fiduciary made a correct decision . . . Nothing in the legislative history suggests that Congress intended that federal courts would function as substitute plan administrators, a role they would inevitably assume if they received and considered evidence not presented to administrators concerning an employee's entitlement to benefits. Such a procedure would frustrate the goal of prompt resolution of claims by the fiduciary under the ERISA scheme.

990 F.2d at 966.

As the *Perry* Court noted, a primary goal of ERISA is to provide a method for workers and beneficiaries to resolve disputes over benefits "inexpensively and expeditiously" and "[p]ermitting or requiring district courts to consider evidence from both parties that was not presented to the plan administrator would seriously impair the achievement of that goal." *Id.* at 967.

In determining whether Defendant's decision was arbitrary and capricious, the Court must consider whether the administrator was operating under a conflict of interest; if so, that conflict must be weighed as a factor in determining whether the administrator acted arbitrarily

and capriciously. *Firestore Tire & Rubber Co. v. Brunch*, 489 U.S. 101, 115 (1989); *Univ. Hosp. of Cleveland v. Emerson Elec. Co.*, 202 F.3d 829, 846 (6th Cir. 2000).

In the case at bar, because Defendant bears the financial cost of paying claims, while making decisions on which claims to pay, "there is an actual, readily apparent conflict of interest" on the part of Defendant. *See Killian*, 152 F.3d at 521. In such a case, the question is whether Defendant's actions vis-a-vis Plaintiff "were improperly influenced by its conflict." *Id.*

IV. Discussion

Plaintiff spends most of her brief addressing an issue that is not before the Court, namely whether the ACI procedure is experimental or investigational. The sole issue before the Court, however, is whether Defendant's decision was arbitrary and capricious in light of the evidence before the administrator and the plan's provisions.[5]

The Sixth Circuit recognized this distinction in *Peruzzi v. Summa Medical Plan*, 137 F.3d 431 (6th Cir. 1998). In *Peruzzi*, Defendant had declined coverage for a treatment consisting of high dose chemotherapy followed by bone marrow transplantation on the grounds that the treatment was of an experimental or research nature. On appeal, Plaintiff cited several cases from other courts that had concluded the procedure was not experimental and should be covered. The Sixth Circuit noted, however, "the proper inquiry addresses not the reasonableness of the treatment itself, but the reasonableness of [Defendant's] determination that it is not covered by

[5] If this were a case in which it were clear that there were no authorities to support the proposition that ACI is investigational, that fact would obviously bear on the question whether Defendant's decision was arbitrary and capricious. In other words, if there were simply no authorities whatsoever to support Defendant's decision, and there were a wealth of authorities concluding that the ACI procedure is not investigational, a stronger argument could be made that Defendant's decision was arbitrary and capricious. As will be discussed in detail below, however, this is not such a case.

the plan." 137 F.3d at 435. Thus, the Court does not need to consider whether the ACI procedure is experimental or investigational in order to make the determination whether Defendant's decision was arbitrary and capricious in light of the plan's provisions.

In connection with her argument that ACI is not investigational, Plaintiff filed two Exhibits with her Amended Motion and Memorandum, which Plaintiff referred to as Exhibits A and B. Exhibit A is a one-page document headed "BlueCross BlueShield Coverage of Autologous Chondrocyte Implantation/Transplantation." Docket No. 37, Ex. A. According to the Supporting Memorandum, Exhibit A "is a list of websites that provide information on whether individual BCBS companies cover ACI." Similarly, Exhibit B is a document headed "BlueCross BlueShield Coverage of Autologous Chondrocyte Implantation/Transplantation." According to the Supporting Memorandum, Exhibit B "is a telephone listing of the companies contacted by Plaintiff's counsel who confirm that ACI is covered and not considered investigational."

Exhibits A and B plainly are not part of the Administrative Record in this case. As has been discussed above, Sixth Circuit authority is clear that the Court in this case is confined to a review of the Administrative Record. Plaintiff herself has previously recognized this proposition and it is curious that Plaintiff attempts simply to "lob in" to the record "evidence" that the Court clearly is not at liberty to consider.

Apparently recognizing this problem, Plaintiff attempts to explain her position as follows:

> This Court, pursuant to its authority under Fed. R. Evid. 201(d), can take judicial notice of the BCBST sister companies that do or do not consider ACI investigational. According to Fed. R. Evid. 201(d), "[a] court shall take judicial notice if requested by a party

> and supplied with the necessary information." Furthermore, "[a] judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). 'Judicial notice may be taken at any stage of the proceeding.' Fed. R. Evid. 201(f).

Docket No. 37, p. 18 n.16.

The Court will decline to take judicial notice of Exhibits A and B for several reasons. First, in determining whether Defendant's decision was arbitrary and capricious, the Court's review is restricted to the Administrative Record. Because these documents are not part of the Administrative Record, the Court believes that it would be inappropriate to take judicial notice of them. Second, the information set forth in Exhibits A and B with regard to whether BlueCross BlueShield Plans in other states offer coverage for ACI surgery is clearly hearsay. Such hearsay appears to be based on either a conversation that one of Plaintiff's counsel had with someone at one of the Plans in question, or upon someone's review of a number of Internet websites. Third, Exhibits A and B both contains columns headed "Offers Coverage (Subject to Medical Criteria)." There is no explanation as to exactly what this means.

Fourth, there is no indication as to when this information was obtained. Obviously, it was obtained prior to April 29, 2005, when the documents were filed with the Court. Defendant's decision to deny Plaintiff benefits was final on June 23, 2004. Even if it were proper for Plaintiff to make the argument that BCBST's decision was arbitrary and capricious because a number of other BlueCross BlueShield plans disagree with it, an appropriate comparison could be made only by evidence showing the positions of the other plans on June 23, 2004.

Fifth, Plaintiff offers no reason for why this information was not presented to Defendant when Defendant was considering Plaintiff's grievance. As has been discussed above, ERISA provides a procedure under which a plan may give authority and discretion to an Administrator to determine eligibility for benefits or to construe the plan, subject to limited review by the Court. Plaintiff clearly had the opportunity to present whatever evidence she wished to Defendant prior to Defendant's making its final decision concerning her claim. Obviously, the Defendant should have had the opportunity to consider this evidence, if relevant, in the first instance, and the goals of ERISA would not be served by this Court's considering evidence that was not presented to Defendant.[6]

The plain language of the Policy at issue gives BCBST the discretion to rely upon medical and scientific literature and the findings of the BlueCross and BlueShield Association Evaluation Center ("TEC"). The Administrative Record contains a TEC document entitled "Autologous Chondrocyte Transplantation of the Knee," which was issued in June 2003. That document sets forth several judgments about whether autologous chondrocyte transplantation for the treatment of clinically significant, symptomatic, focal defects of the articular cartilage of the knee meets TEC criteria. The document addresses the following five TEC criteria: (1) the technology must have final approval from the appropriate governmental regulatory bodies; (2) the scientific evidence must permit conclusions concerning the effect of the technology on health

[6] It should be noted that Defendant filed a "Motion to Strike" Exhibits A and B. The Court will enter a separate Order concerning that Motion.

outcomes; (3) the technology must improve the net health outcome; (4) the technology must be as beneficial as any established alternatives; and (5) the improvement must be attainable outside the investigational settings.[7] According to the document, ACT does not meet four of the five TEC criteria. The document concludes, "For the above reasons, autologous chondrocyte transplantation for the treatment of cartilage defects of the knee does not meet the TEC criteria." Based upon this factor alone, BCBST could have denied coverage for Plaintiff's proposed surgery.

The Administrative Record, however, also contains an excerpt from the BlueCross BlueShield Association "Medical Policy Reference Manual" issued in January 2003 concerning ACT. That portion of the Manual states, "Autologous Chondrocyte Transplantation for the treatment of cartilage defects is considered **investigational**." (Emphasis in original.)

Furthermore, the Administrative Record contains a two-page document entitled "BlueCross BlueShield of Tennessee Medical Policy Manual," which discusses ACI. The effective date of the Policy is May 13, 2004. The "Policy" stated in this document is, "Autologous Chondrocyte Implantation for all conditions is considered ***investigational***." (Emphasis in original). The document further states in part:

> Autologous Chondrocyte Implantation does not meet the following technology evaluation criteria:
>
> The scientific evidence must permit conclusions concerning the affect of the technology on health outcome.
>
> The technology must improve the net health outcome.
>
> The technology must be as beneficial as any established

[7] These criteria correspond to the definition of "Medical Necessity" quoted above.

alternative.

The improvement must be attainable outside the investigational settings.

The document lists 13 articles as "sources." These source articles contain, *inter alia*, the following statements:

> There is insufficient evidence to determine whether ACI is effective for treating cartilage defects of the knee. Three controlled trials were available that compared ACI to computer technologies, which included mosaicplasty and mycrofracture. The results of these trials have not established ACI's efficacy in high-quality trials, and the trials did not provide the most appropriate control group to determine ACI's basic efficacy.[8]
>
> Because hyaline cartilage regenerates over a long period of time, the control trials that followed patients for one year and two years do not provide the long-term evidence needed to reach conclusions about the efficacy of the ACI techniques. Thus far, ACI has not produced durable hyaline cartilage in most patients, and that was the rationale behind the technology's initial development. Adverse events rates cannot be reliably calculated from the small studies that reported such occurrences.[9]
>
> Current available evidence is inadequate to determine the long-term efficacy of ACI for articular cartilage defects of the knee. Because articular cartilage regenerates over several years, the three available controlled trials that followed patients for one year and two years do not provide for long-term evidence needed to reach conclusions about the efficacy of ACI.[10]
>
> The reported literature on ACT and comparators is subject to bias because of the inherent weaknesses of case series. In addition, the long-term impact of conventional surgical treatment or no surgical

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[8] Health Technology Assessment Information Service. Windows on Medical Technology (2004). *Autologous Chondrocyte Implantation For Knee Cartilage Defects.* Dated July, 2004. This source cites over 70 references.

[9] *Id.*

[10] *Id.*

> treatment is poorly documented. The cost-effectiveness analysis is similarly limited by the poverty of the effectiveness data on both ACT and comparators, the lack of long-term follow-up and the lack of empirical data for some of the perimeters in the model used.[11]

While Plaintiff has raised the conflict of interest issue, Plaintiff has presented no evidence showing that the conflict of interest actually influenced Defendant's decision to deny benefits. *See Peruzzi v. Summa Med. Plan*, 137 F.3d 431, 433 (6th Cir. 1998). Plaintiff presented no evidence concerning the cost of the ACI procedure, and no evidence concerning how that cost would impact the financial condition of Defendant.

Moreover, as discussed above, Defendant had substantial evidence on which to make its determination that ACI is investigational. This is not a "close" case, where Defendant might have been tempted to allow its conflict of interest to color its judgment on the underlying issue. There is substantial evidence in the record to justify Defendant's decision. That fact, coupled with Plaintiff's complete lack of evidence concerning how Defendant's conflict of interest actually impacted the decision in this case, is fatal to Plaintiff's argument.[12]

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[11] Jobantatra, P., Parry, D., Fry-Smith, A., & Buris, A. (2001). Effectiveness of Autologuos Chondrocyte Transplantation for Hyaline Cartilage Defects in the Knees: A Rapid and Systematic Review. *Health Technology Assessment*, 5 (11). This source cites over 100 references.

[12] Following the filing of Plaintiff's Amended Motion for Judgment on the Administrative Record and supporting Memorandum, Plaintiff submitted a letter to the Court enclosing a recently decided Sixth Circuit Opinion, *Calvert v. Firstar Finance, Inc.*, United States Court of Appeals for the Sixth Circuit, No. 03-5815, decided May 17, 2005. The letter stated, "The Opinion may be relevant in this Court deciding the above-styled case." Thereafter, the undersigned entered an Order granting Plaintiff leave to file a supplemental brief concerning the application of *Calvert*. Plaintiff filed her supplemental brief on June 17, 2005. The *Calvert* Court recognized the proposition that a conflict of interest is to be considered in applying the arbitrary and capricious standard. The *Calvert* Court further stated:

Plaintiff makes several further arguments that should be addressed. First, Plaintiff persists in arguing that the Administrative Record should consist only of documents submitted to the Level II Grievance Committee, apparently on the theory that it was somehow improper for the Medical Policy Review Committee to be involved in the decision to deny Plaintiff benefits. The Court ruled upon this issue in an Order entered April 14, 2005, in response to Plaintiff's "Motion to Strike Certain Documents Filed by Defendant." As is reflected in that Order, Plaintiff had taken the position that documents favorable to Defendant's position, which were unquestionably considered by the Medical Policy Committee, should not be part of the Administrative Record apparently because those documents had not been submitted to the Level II Grievance Committee. In response to Plaintiff's arguments, the Court stated in pertinent part as follows:

> Moreover, Plaintiff's position is difficult to accept. Plaintiff initially filed her Motion to Supplement Administrative Record arguing that documents supporting her position, which she had submitted to the Medical Policy Review Board, should be part of the Administrative Record. BCBST agreed with Plaintiff and submitted those documents as part of the Administrative Record. BCBST also submitted documents unfavorable to Plaintiff's position, which documents were also before the Medical Policy

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> The Court would have a better feel for the way to accord this conflict of interest if *Calvert* had explored the issue through discovery. While Calvert's counsel asserted that it was his understanding that discovery is never permissible in an ERISA action premised on a review of the Administrative Record, an exception to that rule exists where a Plaintiff seeks to pursue a decision-maker bias.

Calvert v. Firstar Finance, Inc., slip op., p. 5 n.2.

It is important to note that Plaintiff in the case at bar, even though she cited *Calvert* for other propositions, has never sought discovery from Defendant concerning this issue.

> Review Board prior to the time BCBST made its final decision. Plaintiff now objects to the inclusion of these latter documents in the Administrative Record, however, on the theory that these documents were never submitted to the Level II Grievance Committee.
>
> It appears that Plaintiff wishes to have documents supporting her position included in the Administrative Record, while having documents contrary to her position excluded from the Administrative Record. The Court sees no basis for such an argument. Furthermore, Plaintiff's argument seems particularly inconsistent in view of the fact that there is nothing in the record of this case to indicate that the documents Plaintiff sent to the Medical Policy Review Board (that Plaintiff wished to include in the Administrative Record) were ever submitted to the Level II Grievance Committee.

For whatever reason, Plaintiff continues to make an argument that the Court has previously ruled upon. Plaintiff states in her Memorandum in support of her Amended Motion for Judgment on the Administrative Record in part:

> Although the Court denied [Plaintiff's] Motion to Strike, the Court does not [*sic*] and should not consider documents not submitted to the Level II Grievance Committee. . . . Here, there is not a shred of evidence in the entire Administrative Record that BCBST submitted any articles of other evidence to the Level II Grievance Committee or, more importantly, that the Level II Grievance Committee actually considered any articles or evidence supporting BCBST's position. Likewise, the Policy is clear that it is the Level II Grievance Committee that was charged with reviewing [Plaintiff's] claim. . . . In contrast, all of [Plaintiff's] materials were submitted directly to Mr. Touse, the Chair of the Level II Committee, or to Shelly Sullivan, Touse's assistant and a member of the Level II Committee.

Moreover, Plaintiff's Memorandum states in part, "[Plaintiff] adamantly rejects the notion that the Medical Policy Committee was entitled to make the final decision on her denial of benefits claimed. Instead, [Plaintiff] relies on the Policy which unequivocally indicates that the Level II Grievance Committee must review denial of benefit claims." (Underlining in

original.)

Plaintiff's position is not well-taken. As the Hearing transcript plainly shows, Plaintiff's own counsel agreed that he wanted the Medical Policy Review Committee to reconsider its decision that ACI was investigational. Plaintiff cannot now argue that it was somehow improper for the Medical Policy Review Committee to be involved in deciding Plaintiff's claim.

Second, Plaintiff argues that "this case is filled with indicia of arbitrariness that this Court should consider," namely: (1) Defendant's reliance on the "research opinion" of a BCBST nurse; (2) Defendant's unwillingness to weigh all of the relevant evidence; (3) the manner in which the Level II Grievance Committee reached its decision; and (4) the unwillingness of BCBST to allow Plaintiff the opportunity to rebut the evidence that the Medical Policy Committee reportedly relied upon. These points will be discussed below.

Plaintiff argues that the Medical Policy Review Board should not have "relied" upon "the research and findings of a nurse." (Underlining in original.) Plaintiff apparently argues that the Medical Policy Review Board and/or its Medical Technology Assessment Subcommittee should have relied upon their own research and analysis or "the experience and knowledge of the distinguished orthopaedic surgeons that testified on behalf of [Plaintiff]." Plaintiff also argues that the nurse's report is "incomplete, inaccurate, and misleading."

Taking the second argument first, Plaintiff's claim that the nurse's report is incomplete, inaccurate, and misleading, is based upon evidence in Exhibits A and B, which the Court has declined to notice for reasons discussed above. Second, Plaintiff bases her argument concerning what the Medical Policy Review Board and/or the Medical Technology Assessment Subcommittee should have done, upon a portion of Defendant's Memorandum in support of its

Motion for Judgment on the Administrative Record. In its Memorandum, Defendant stated in pertinent part as follows:

> The Medical Policy Review Board establishes BCBST medical policy regarding whether a given procedure, treatment, or drug is medically appropriate, medically necessary, cosmetic, experimental, or investigational, etc. Initially, another committee, the Medical Technology Assessment Subcommittee, which consists entirely of BCBST physicians and outside physicians, reviews the policy and conducts all research. The Technology Committee then makes a recommendation to the Board whether BCBST medical policy should change.

Obviously, nothing in this "policy" prevents the Medical Technology Assessment Subcommittee or the Medical Policy Review Board from considering the report or recommendation of a registered nurse. Plaintiff complains that the registered nurse had "no demonstrated expertise in orthopaedics." That fact, however, is completely beside the point.

Plaintiff complains of Defendant's "unwillingness to weigh all of the relevant evidence." This is simply a variation of the argument that ACI is not investigational, an argument that is irrelevant in this case, and that has been discussed above.

Plaintiff next complains of "the manner in which the Level II Grievance Committee reached its decision." That argument is, at least in part, a rehash of Plaintiff's complaint that the Medical Policy Committee should not have been involved in the decision on Plaintiff's claim, even though her own counsel specifically agreed with that procedure. Plaintiff argues in part as follows:

> The manner in which the Level II Grievance Committee reached its decision is highly suspect. The Committee's behavior expresses a body not interested in hearing evidence, but a body that wanted to rubber stamp a denial. The Committee informed Ms. Simmons that she is entitled to attend a hearing and to present her side of the case, yet she was limited to "10" minutes to do so. .

> . . When Ms. Simmons' case was convened at the Hearing, Ms. Simmons was represented by counsel and prepared to put on evidence of the non-investigational nature of ACI, but the Committee made clear that her time is limited because they need to get through the rest of their agenda for that day. . . . Then, surprisingly, the Committee informs Ms. Simmons that they probably are not medically qualified to make this decision and that they will likely rely on the Medical Policy Committee in making their decision.

Once again, Plaintiff's complaints here are not well-taken. The Hearing Transcript is 32 pages long. Plaintiff was represented by counsel, who presented the testimony of two witnesses. Based upon these facts, the Court finds it difficult to believe that the hearing actually was limited to 10 minutes (even though Plaintiff apparently had been advised that it would be). In any event, Plaintiff's counsel never complained at the hearing that he did not have enough to time to present the evidence and arguments that he wished to present. Furthermore, Plaintiff continues to stretch the facts when she argues that, "surprisingly, the Committee informed Ms. Simmons that they probably are not medically qualified to make this decision and that they will likely rely on the Medical Policy Committee in making their decision." A review of the Hearing Transcript shows that Plaintiff's own counsel clearly wished to have the Medical Policy Committee become involved in the determination of Plaintiff's claim.

Plaintiff next argues that she did not have an opportunity to rebut the evidence that the Medical Policy Committee purportedly relied upon. Despite her apparent desire that the Court conclude otherwise, the record plainly shows that Plaintiff was given an opportunity to submit whatever materials she wished directly to the Medical Policy Committee. There is nothing anywhere in the record to indicate that Plaintiff had a right to submit evidence to "rebut" anything considered by the Medical Policy Review Committee. Additionally, there is nothing in

the record to indicate that Plaintiff ever attempted to submit any "rebuttal" evidence to the Medical Policy Review Committee between the time of its denial and the filing of this lawsuit.

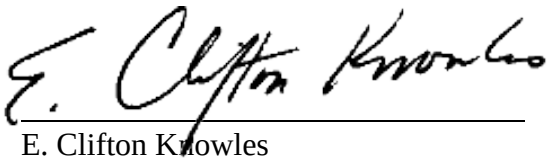
Finally, as discussed above, Plaintiff filed a supplemental brief, with leave of Court, concerning the application of *Calvert v. Firstar Finance, Inc.*, and Defendant has filed a Response to that Brief. Plaintiff essentially argues that *Calvert* shows that even using the least demanding form of review, a court can hold that an administrator acted arbitrarily and capriciously. The Court would agree with this proposition but, as Plaintiff herself recognizes, *Calvert* is not identical to the present case. In *Calvert*, the Court focused on the administrator's failure to acknowledge or consider pertinent aspects of the claimant's medical records, such as CT scans and x-rays. The administrator in *Calvert* found "that there was no objective data in the record to support the conclusion that [claimant] suffered from any disability or any functional limitation." As the *Calvert* Court stated, "This conclusion simply does not square with the verifiable objective results of [claimant's] x-rays and CT scans . . . ." Thus, *Calvert* is clearly distinguishable from the case at bar.

Plaintiff further argues that the *Calvert* Court addressed certain specific ERISA issues, namely: (1) the Administrative Record alone, without the inclusion of evidence obtained through discovery, can provide sufficient proof that an insurer's conflict of interest played a role in the decision-making process; (2) the *Calvert* Court examined the totality of the circumstances in determining whether a denial of benefits was arbitrary and capricious; and (3) most importantly, the *Calvert* Court made clear that the arbitrary and capricious standard does not mean "impossible." The facts cited by Plaintiff to support these arguments have been addressed above.

V. Conclusion

Defendant's decision to deny Plaintiff benefits in the case at bar was not arbitrary and capricious but was rational in light of the Plan's provisions.

An appropriate Order will be entered.



E. Clifton Knowles
United States Magistrate Judge